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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,020	10/16/2001	Daniel S. Kohane	0492611-0417 (MIT 8966)	5504
24280	7590	12/07/2004	EXAMINER	
Choate, Hall & Stewart			FUBARA, BLESSING M	
Exchange Place			ART UNIT	
53 State Street			PAPER NUMBER	
Boston, MA 02109			1615	

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,020

Applicant(s)

KOHANE ET AL.

Examiner

Blessing M. Fubara

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-65 and 80-85 is/are pending in the application.
- 4a) Of the above claim(s) 21,22,26,29,31-36 and 38-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-20, 23-25, 27, 28, 30, 37, 46-65 and 80-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, 131 declarations by Dr. Dr. Daniel S. Kohane, amendment and remarks, all filed 07/15/04. Claims 1, 2, 6-65 and 80-85 are pending and of these claims, 21, 22, 26, 29, 31-36 and 38-45 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1, 2, 6-20, 23-25, 27, 28, 30, 37, 46-61 and 80-85 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn because applicants argue that microparticles disclosed in the instant specification at page 3, lines 8-11 provide a teaching of solid microparticles and this argument is persuasive.

Claim Rejections - 35 USC § 102

2. Claims 63 and 64 remain rejected under 35 U.S.C. 102(b) as being anticipated by Moynihan (US 5,589,189).

Applicants argue that Moynihan does not disclose the instant solid microparticles because liposomes are not solid microparticles.

3. Applicants' arguments filed 07/15/04 have been fully considered but they are not persuasive.

Liposomes are microparticles and microparticles are solid according to applicants' argument regarding the 35 USC 112, first paragraph.

131-Declaration and the Bot Reference

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The declaration by Dr. Kohane attempts to remove Bot as prior art as Dr. Kohane in a signed declaration states that the instant invention was conceived before January 06, 2000. Specifically, the declaration refers to exhibit B where the nifedipine particles are encapsulated in a matrix of lactose, DPPC and albumin; bupivacaine particles are also encapsulated in the same matrix. Claims 1, 2, 6, 7, 13, 17-20, 23-25, 27, 28, 30, 37, 46, 48-53, 57-60, 62-65 and 80-85 remain rejected under 35 U.S.C. 102(a) as being anticipated by Bot et al. (WO 00/00215) because the scope of the declaration is not commensurate with the scope of the claims since the scope of the claims is broader and claim 1, for example, is directed to an agent encapsulated in a matrix of lipid, protein and sugar; and exhibit B relates to encapsulating nifedipine and bupivacaine.

Claim Rejections - 35 USC § 103

4. Claims 1, 2, 6, 7, 13, 16, 18-20, 23-25, 27, 28, 30, 37, 46 and 57-61 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Moynihan (US 5,589,189).

Applicants traverse the rejection on the basis that Moynihan does not disclose or suggest solid particles since liposome is not a particle and is not a solid particle and that there is no reasonable expectation that lyophilization of the liposome will produce solid particles.

5. Applicants' arguments filed 07/15/04 have been fully considered but they are not persuasive.

Applicants admit on page 14 of the remarks filed 07/15/04 that microparticles are solid and by this admission liposomes, which are microparticles are also solid. Lyophilization generally leads to the removal of moisture and to solid. Applicants do not show that lyophilization would not lead to solid particles.

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6. Claims 1, 2, 6, 7, 12-20, 23-25, 27, 28, 30, 37, 46-65 and 80-85 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al. (US 6,423,345).

Applicants traverse the rejection on the basis that Bernstein does not particularly disclose, teach or suggest the claimed combination of proteins, sugar, lipid and synthetic polymer since Bernstein provides a general teaching that synthetic polymer, lipid, protein and sugar can all be used to form matrix of solid particles. Applicants further state that claims 6, 82 and 83 do not include lipid as part of the polymeric matrix while Bernstein teaches lipid as part of the polymeric matrix.

7. Applicants' arguments filed 07/15/04 have been fully considered but they are not persuasive.

Regarding claims 6, 82 and 83, the claimed composition comprises... and the comprising language does not exclude lipid as part of the polymeric matrix. The above rejection is not an anticipatory rejection but a rejection based on the finding that the said claims above are obvious over Bernstein. Since Bernstein discloses a drug delivery composition that comprises polysaccharide and lipid or protein and lipid, a third composition can be formed from combination of the two composition for the same topical drug delivery; and the "idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

8. Claims 8-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al. (US 6,423,345) and further in view of Goldenheim et al. (US 6,534,081).

Applicants argue that the combination of Goldenheim and Bernstein cannot render the claims obvious because the combined teaching do not teach all the elements of

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the claims since Bernstein does not teach the combination of lipid, protein, sugar and synthetic polymer.

9. Applicants' arguments filed 07/15/04 have been fully considered but they are not persuasive.

As stated above, "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose" and thus Bernstein disclose a composition that is obvious over the claims. Thus the combination of Goldenheim and Bernstein renders the claims obvious.

10. Claims 47, 54-56 and 61 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bot et al. (WO 00/00215).

Applicants argue that Bot is removed as a prior art by the declaration of Dr. Kohane.

11. Applicants' arguments filed 07/15/04 have been fully considered but they are not persuasive.

Bot remains a prior art because the scope of the declaration is not commensurate with the scope of the claims since the scope of the claims is broader and claim 1, for example, is directed to an agent encapsulated in a matrix of lipid, protein and sugar; and exhibit B relates to encapsulating nifedipine and bupivacaine. Therefore, claims 47, 54-56 and 61 remain obvious over Bot.

12. Claims 8-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bot et al. (WO 00/00215) in view of Goldenheim et al. (US 6,534,081).

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Applicants argue that because Bot is removed as prior art by the declaration of Dr. Kohane, the rejection immediately above cannot stand.

13. Applicants' arguments filed 07/15/04 have been fully considered but they are not persuasive.

Bot remains a relevant prior art because the scope of the declaration is not commensurate with the scope of the claims since the scope of the claims is broader and claim 1, for example, is directed to an agent encapsulated in a matrix of lipid, protein and sugar; and exhibit B relates to encapsulating nifedipine and bupivacaine.

Other Matters:

Claims 21, 22, 26, 29, 31-36 and 38-45 are withdrawn from consideration. However, applicants' list of the pending claims does not identify the withdrawn claims with the appropriate status identifiers. Correction is respectfully requested.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

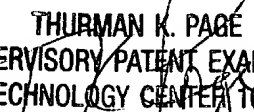
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Blessing Fubara
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